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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,078	06/08/2006	Jianming Chen	601/5	6889

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

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01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,078	CHEN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 21* is/are pending in the application.

4a) Of the above claim(s) *5, 8 - 12, 15 - 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 4, 6, 7, 13, 14, 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed November 26, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 6 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Other than the specific derivatives of starch and cellulose found in claim, “starch and their derivative” and "cellulose and their derivatives” were rejected under the written description provision as the specification provide insufficient written description to support the full genus encompassed by these terms. This rejection is MAINTAINED for the reasons set forth in the Office Action mailed July 29, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that there is a strong presumption that the original claims are supported in the application as filed, and whether or not the meaning if “derivatives of starch” is clear, the original claim supports

itself. Such a person would also know that this term would refer to the functional equivalents of starch or cellulose.

These arguments are not found to be persuasive. Applicant has not provided any indication of the extent of modification that occur to each of these components while remaining a derivative. There is nothing in the claims or specification that limits the term "derivative" to only functional equivalents. Depending on the exact function of the starch or cellulose in a formulation, and possibly the amount of the ingredient present in the formulation, those compound(s) that are functional equivalent to starch or cellulose are not necessarily the same subset of compounds. Therefore, the specification and original claims provide insufficient written description to support the full genus encompassed by these terms and this rejection is MAINTAINED.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 6, 13, 14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons set forth in the Office Action mailed July 29, 2008 and those set forth below. Newly added claim 21 is now included in this rejection.

Applicant traverses this rejection on the grounds that the entire claim must be considered, including the preamble, as the Examiner has refused to consider the preamble limitation of “drop pill”. There can be little doubt that “drop pill” is structure and has meaning only when the specification is considered. The meaning of the term is defined throughout the specification and refers to a pharmaceutical product prepared by dripping a solution, suspension or emulsion of the drug and the adjuvant into a coolant. The preamble gives life and meaning to the claims and as such is limiting. As Okada does not disclose drop ills, it fails to disclose each and every claim limitation in a single prior art reference and is therefore not anticipatory.

These arguments are not found to be persuasive. The Examiner has considered the entirety of the claim. The limitations from the specification in regards to “drop pill” which Applicant has described are product-by-process limitations, the end result of the process being a solid pharmaceutical dosage form. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. The product produced by Okada et al. is an suspension that is put into molds and dried to produce a solid pharmaceutical dosage form. So even if the preamble is afforded patentable weight, Applicant has not

demonstrated that the different processes result in products which are different and non-obvious.

Newly added claim 21 takes the limitation previously found in claims 6 regarding water and places it in a separate dependent claim. As all of the ingredients are not supplied in their anhydrous forms, the compounds used by Okada et al. contain water in their crystal structure.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 4, 6, 7, 13, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons set forth in the Office Action mailed July 29, 2008 and those set forth below. Newly added claim 21 is now included in this rejection.

Applicant traverses this rejection on the grounds that the limitation of "drop pill" is not found in cited prior art and that the Examiner has not shown that one skilled in the art would have a reasonable expectation of success to modify Okada in the direction of the drop pill, as there is no apparent reason to modify the air-dried product formulation in the direction of drop pills.

These arguments are not found to be persuasive. Arguments regarding the "drop pill" limitation present in the preamble have been discussed in greater detail above. Air-drying versus dosage formation in coolant are product-by-process limitations, which were also discussed in greater detail above. This rejection is MAINTAINED.

Newly added claim 21 takes the limitation previously found in claims 6 regarding water and places it in a separate dependent claim. As all of the ingredients are not

supplied in their anhydrous forms, the compounds used by Okada et al. contain water in their crystal structure.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW